

Remarks

Claims 1-15 were pending in the subject application. By this Amendment, the applicants have amended claims 1, 5, and 14, and added new claims 16-19. No new matter has been introduced. Support can be found throughout the original specification and claims (see, e.g., page 5, lines 8-9; page 1, lines 29-31; page 3, lines 13-14; and page 4, lines 27-29). Accordingly, claims 1-19 are before the Examiner for further consideration.

The amendments to the claims have been made in an effort to lend greater clarity to the claimed subject matter and to expedite prosecution. These amendments should not be taken to indicate the applicants' agreement with, or acquiescence to, the rejections of record. Favorable consideration of the claims now presented, in view of the remarks and amendments set forth herein, is earnestly solicited.

Claims 1, 2, 4-6, and 14-15 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lowe *et al.* (US Patent No. 5,989,923) and Stephens *et al.* (GB 2054995A). The applicants respectfully traverse this ground for rejection.

The applicants would like to emphasize the surprising ability of the claimed invention to deal with issues caused by light coming from several different directions, or what might be termed "directional" issues. When using a sensor for detection of an analyte, it is not always possible to shine light so that it is well-aligned with the point of analyte detection, for capture and reflection. This can be a problem in many different applications, such as subcutaneous implants. The subject invention can allow for sensing using a subcutaneous implant, as well as a wide range of other applications. Unlike the related art, the claimed invention allows a light source to be pointed in what is merely approximately the right alignment and direction, and achieves sensing. These surprising advantages of the subject invention stem from the use of a hologram formed as a non-planar mirror.

The Action asserts at page 5 that it would have been obvious to a person of ordinary skill in the art at the time the invention was made "to modify the device of Lowe *et al.*, as taught by Stephens *et al.*, in order to guide light with the narrowest possible bandwidth to the holographic surface so that the colors reflected are indicative of the part of the reflector from which it is received." However, the applicants respectfully submit that this assertion is not valid in light of the

teachings of Stephens *et al.* because both the Stephens *et al.* reference and the subject invention disclose guiding broadband white light to a hologram surface. Thus, a skilled artisan would not have modified the teachings of Lowe *et al.* with the unit of optical fibers for transmitting light to and from a hologram, as taught by Stephens *et al.*, in order to guide light with the narrowest possible bandwidth to the holographic surface. Such a modification would not have made sense since Stephens *et al.* teach guiding broadband white light to the holographic surface, not light with a narrow bandwidth.

Thus, the question of whether narrowband light can or cannot be guided in Stephens *et al.* is not relevant. Rather, the relevant consideration should be whether or not the teaching in Stephens *et al.* of white light illuminating the hologram surface and the reflected narrowband light being guided to the receiving fiber, in combination with Lowe *et al.*, renders the claimed invention obvious. The applicants submit that it does not.

The device of Stephens *et al.* is configured such that each holographic element in each fiber optic channel reflects narrow bandwidth light of a specific wavelength onto the receiving fiber when illuminated by white light. This means that each element must be recorded with a specific wavelength at a defined angle of illumination so that the required reflected wavelength is directed at close to the normal angle necessary for sufficient intensity to be captured by the receiving fiber optic. This works because the distance between the illuminating fiber end and the element is small and the fibers are mounted in a perpendicular orientation to the elements, as shown in Figure 1 of Stephens *et al.* It can be seen from this that such a condition can be clearly achieved by a planar hologram; the constrained geometry of the device enables this mode of operation. As disclosed at page 1, lines 81-85, non-planar holographic elements have a wider frequency response than planar ones (i.e. reflect a broader range of wavelengths). Using such a non-planar holographic element would clearly be disadvantageous for the Stephens *et al.* device, as the broader range of wavelengths reflected would introduce the possibility of cross-talk between the channels. Thus, a skilled artisan would not have had any reason to combine the teachings of Stephens *et al.* with any device utilizing a non-planar holographic element.

In the subject invention, the configuration can be different from that of Stephens *et al.* in the following ways:

- white light can be illuminated from a distance
- there is a relatively large range of orientations at which light can be incident on the sensor
- the angle of orientation can be uncontrolled.
- the reflected wavelength can vary, corresponding to the response of the sensor to the analyte.

If this device were fabricated using a planar sensor, then at a given Bragg grating condition, different wavelengths would be reflected at different angles. For a given angle of orientation of the transmitting fiber, one wavelength would be reflected back onto the receiving fiber. However, if the orientation were to change, a different wavelength would be reflected onto the receiving fiber, and thus the device would be incapable of registering a unique reflected wavelength dependent on a single Bragg condition, and hence sensor response.

In contrast to the device of Stephens *et al.*, the use of a concave/convex (non-planar) grating in the claimed invention provides significant advantages because any wavelength satisfying the Bragg condition in the hologram is reflected back onto the receiving fiber, independent of orientation. When the Bragg condition is changed, the changed wavelength is still reflected to the fiber, irrespective of whether the orientation is the same or not. Such a configuration and the role of the concave/convex (non-planar) element are not required for the Stephens *et al.* device; they are neither taught nor suggested in Stephens *et al.*.

Thus, a skilled artisan would not have had any reason to modify Lowe *et al.* with the teachings of Stephens *et al.* to arrive at the claimed invention. The mere fact that the purported prior art could have been modified or applied in some manner to yield an applicant's invention does not make the modification or application obvious unless "there was an apparent reason to combine the known elements in the fashion claimed" by the applicant. *KSR International Co. v. Teleflex Inc.*, 550 U.S. 550 U.S. 398, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). Also, an applicant's invention is not "proved obvious merely by demonstrating that each of its elements was, independently, known in the (purported) prior art." *Id.* Though the Action has alleged a reason to combine the cited references

(to guide light with the narrowest possible bandwidth to the holographic surface), the applicants submit that the assertion on which the reason is based is not correct and that a skilled artisan would not have found such a reason to modify Lowe *et al.* with the teachings of Stephens *et al.*

Moreover, by this Amendment, independent claims 1, 5, and 14 have been amended to recite that “an optical characteristic of the hologram changes as a result of a variation of a physical property of the medium resulting from interaction with the analyte.” The applicants would like to emphasize that the claimed invention utilizes a sensor for the detection of an analyte, which senses based on interaction with the analyte. The Stephens *et al.* reference, on the other hand, teaches an optical position encoder and is not a disclosure of a sensor for an analyte. Neither the Lowe *et al.* reference nor the Stephens *et al.* reference addresses or even contemplates the particular problem which the claimed invention overcomes, i.e. detecting an analyte in an environment where there is considerable light scatter (in several applications, including, for example, in subcutaneous implants).

Furthermore, the applicants note that the Action indicates in paragraph 2 that “the claims do not specify that the recording surface of the mirror hologram is formed as a non-planar surface.” While the applicants do not believe that such a recitation is necessary to overcome the rejections of record, in order to provide further distinction over the combination of cited references, new claims 16-19 have been added. Claims 16-19 each recite that the recording surface of the non-planar mirror is formed as a non-planar surface.

As discussed above, a skilled artisan would not have had a reason to combine Lowe *et al.* and Stephens *et al.* to arrive at the claimed invention. Additionally, the subject invention provides surprising advantages, such as dealing with “directional” issues of light on the hologram. Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection based on the combination of Lowe *et al.* and Stephens *et al.*

Claims 3 and 7-13 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lowe *et al.* in view of Stephens *et al.* as applied to claims 1 and 5 above, and further in view of Mizutani *et al.* (US Patent No. 6,483,611). The applicants respectfully traverse this ground for rejection.

The arguments presented above with respect to the rejection based on Lowe *et al* and Stephens *et al*. are hereby incorporated in their entirety. Mizutani *et al*. do not cure or even address the deficiencies of Lowe *et al*. Specifically, there is no reason a skilled artisan would have combined Lowe *et al*. and Stephens *et al*. to arrive at the claimed invention.

Accordingly, the applicants respectfully request reconsideration and withdrawal of the rejection based on the combination of Lowe *et al*., Stephens *et al*., and Mizutani *et al*.

In view of the foregoing remarks and the amendment above, the applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

The applicants also invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephone interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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